K123369
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5. 510(K) SUMMARY

for the LightLab Imaging, Inc.
ILUMIEN OPTIS
(per 21CFR 807.92)

JAN 30 2013

1. SUBMITTER/510(K) HOLDER

LightLab Imaging, Inc.
4 Robbins Road
Westford, MA 01886

Contact Person: Jeffrey Roberts
Telephone: 978-577-3451

Date Prepared: 10/25/12

2. DEVICE NAME

Proprietary Name:	ILUMIEN OPTIS
Common/Usual Name:	Ultrasonic pulsed echo imaging system
Classification Name:	Ultrasonic pulsed echo imaging system

3. PREDICATE DEVICE

- C7 XR™ Imaging System with Fractional Flow Reserve (FFR) (ILUMIEN Guided Therapy System) manufactured by LightLab Imaging, Inc., K111201.

4. DEVICE DESCRIPTION

The ILUMIEN OPTIS is a cart-mounted computer and Imaging Engine (or optical engine) placed inside an ergonomically designed mobile cart. It also includes the Drive-motor and Optical Controller (DOC), which provides the interconnection between the ILUMIEN OPTIS System and the Dragonfly Catheter. The cart is equipped with two display monitors (one for the console operator, and the other for the physician), as well as a keyboard and mouse. The cart also contains an isolation transformer for electrical safety.

The cart includes two USB mounted FFR receivers which provide wireless reception of distal intracoronary and aortic pressure signals originating at the PressureWire® Aeris

and the aortic pressure transducer (AIU). These signals are used to calculate and display the patient's Fractional Flow Reserve (FFR) on the system monitor.

5. Intended Use

The ILUMIEN OPTIS with Dragonfly™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The ILUMIEN OPTIS will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

6. Technological Characteristics and Substantial Equivalence

The ILUMIEN OPTIS is an upgrade to the previously cleared predicate device C7 XR™ Imaging System with Fractional Flow Reserve (FFR) (ILUMIEN Guided Therapy System) manufactured by LightLab Imaging, Inc. The ILUMIEN OPTIS is substantially equivalent to the C7 XR™ Imaging System with Fractional Flow Reserve (FFR) (ILUMIEN Guided Therapy System) based on intended use, indication for use, typical clinical use, operational characteristics, and fundamental technology characteristics.

The ILUMIEN OPTIS represents an upgrade to the predicate device in terms of performance through the same Drive-motor and Optical Controller (DOC) design and technological characteristics including an increase in engine A-scan rate, frame rate, pullback speeds, and pullback length. The pullback time, display option, and automated lumen measurement have also been upgraded.

7. Performance Testing

The ILLUMIEN OPTIS has been tested and is in compliance with UL Standard No 60601-1, Medical Electrical Equipment Part I: General Requirements for Safety, IEC 60601-1-2 Ed. 2.1, Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment, EN 60601-1-2:2007, Electromagnetic emissions and immunity requirements for medical

electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment, IEC 60825-1, 2nd, Ed., 2007, SAFETY OF LASER PRODUCTS – Part 1: Equipment classification and requirements, DICOM Standard (PS 3.2-2008), 21 CFR 1040.10, Performance Standards for Light-Emitting Products, Laser Products, and CFR 47 FCC Part 15 Subpart B Class B emissions requirements (USA).

In addition to the electrical safety testing performed, software verification and validation was conducted to FDA regulations and guidance document requirements. The results of this testing conclude the software has met these requirements. Design verification and validation was also performed on the ILUMIEN OPTIS in compliance with internal design control procedures which included bench testing. This testing included physical, mechanical, and optical characteristics testing. The system hardware was evaluated for range, speed, and rotation accuracy and durability. Optical testing was conducted and included scan range and rate, resolution, and sensitivity. The results of this testing concludes the ILUMIEN OPTIS is determined to be safe and effective and is substantially equivalent to the predicate device C7 XR™ Imaging System with Fractional Flow Reserve (FFR) (ILUMIEN Guided Therapy System).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 30 2013

LightLab Imaging, Inc.
C/O Mr. Jeffrey Roberts
Principal Regulatory Affairs Specialist
4 Robbins Rd.
Westford, MA 01886

Re: K123369
Trade/Device Name: Ilumien Optis
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: NQQ
Dated: October 25, 2012
Received: November 1, 2012

Dear Mr. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K123369

Device Name: ILUMIEN OPTIS

Indications for Use:

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Prescription Use __X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S